A Tiered Approach to Assessing Children's Exposure

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EPA/ACC Technical Workshop for the Voluntary Children's Chemical Evaluation Program, December 2001

Presentation Contents

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- Unique aspects of child exposure
- Data needs & sources
- Overview of tiered approach
- Conclusions
- Discussion/ Questions?

Background

- Development supported by the American Chemistry Council
- Approach is detailed in Environmental Health Perspectives, Armstrong et al. 2000, 108 (6): 469-474; Toxicology Letters (in press 2002)
- Approach developed early in VCCEP discussions
  - chemical selection not yet done

Goal

- Efficiently identify the substances and scenarios that present the highest potential risks to children
- Help focus on chemicals:
  - to which children may be most exposed AND
  - with highest potential risk
- Consistent with VCCEP risk-based goal:
  - "to better understand the potential health risks to children associated with certain chemical exposures"

Key Considerations

- Focus is on children
  - Considers unique aspects of child exposure
- Risk-based
  - requires integration of hazard and exposure information
- Sophistication of the exposure assessment is aligned with:
  - the overall risk characterization goals
  - the hazard data

Unique Aspects of Child Exposure

- Exposure assessment guidance exists, but not tailored specifically to children:
  - US EPA Guidelines for Exposure Assessment (EPA 1992)
  - The Practice of Exposure Assessment: A State of the Art Review (Paustenbach 2000)
- Needed - supplemental guidance & data:
  - application of the approaches to children
  - more specific data for children
  - relevant activity and exposure scenarios

Unique Aspects of Child Exposure:
Differential Exposure Potential

Comparison of Child and Adult Intakes

Source: US EPA 1997, NRC 1993 and Gephart 1994

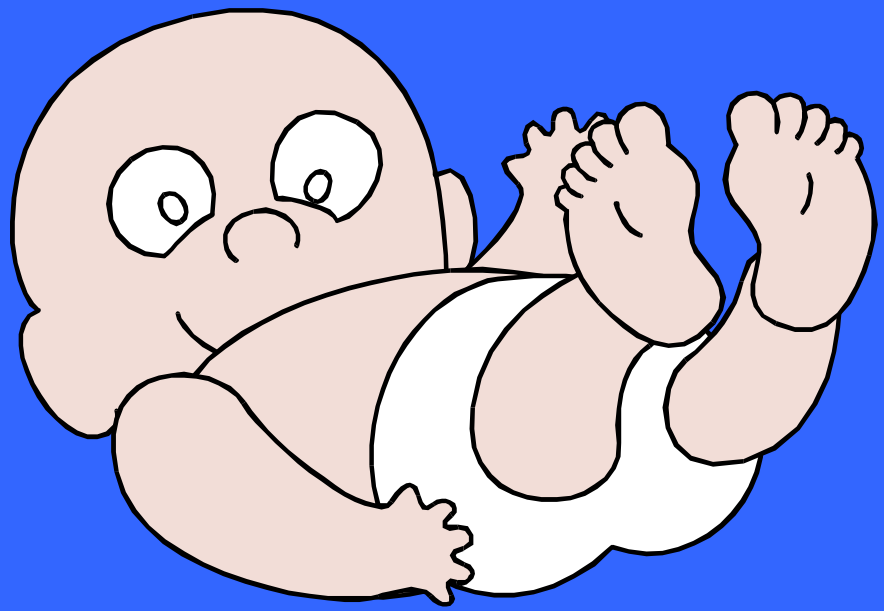
Media	Child (<1 yr.)	Adult	Ratio (Child / Adult)
Air	0.44 m^3/kg-day	0.19 m^3/kg-day	2.3
Water/fluids*	161 g/kg-day	33.5 g/kg-day	4.8
Food	140 g/kg-day	23 g/kg-day	6.1

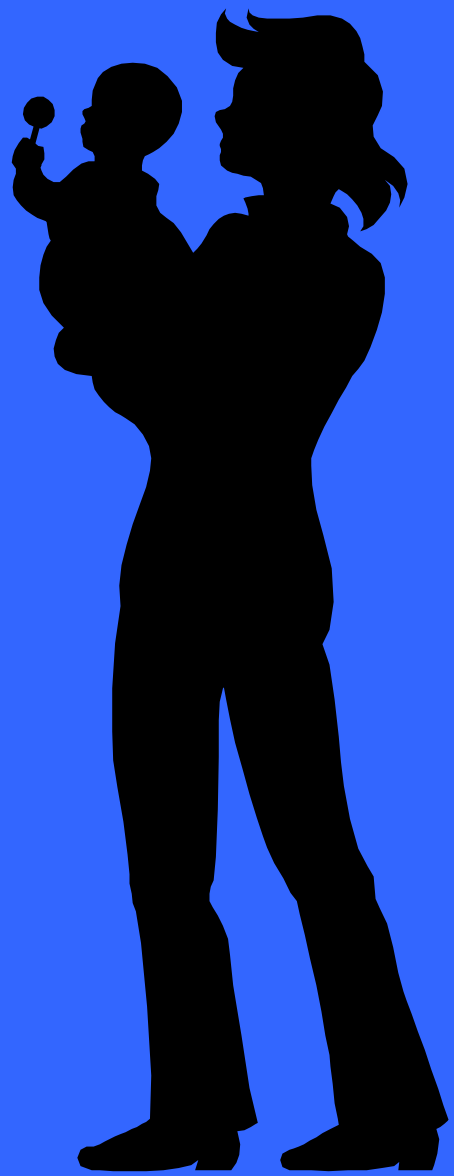
*Also, children's beverage and food *preferences* can differ greatly from those of adults (NRC 1993)

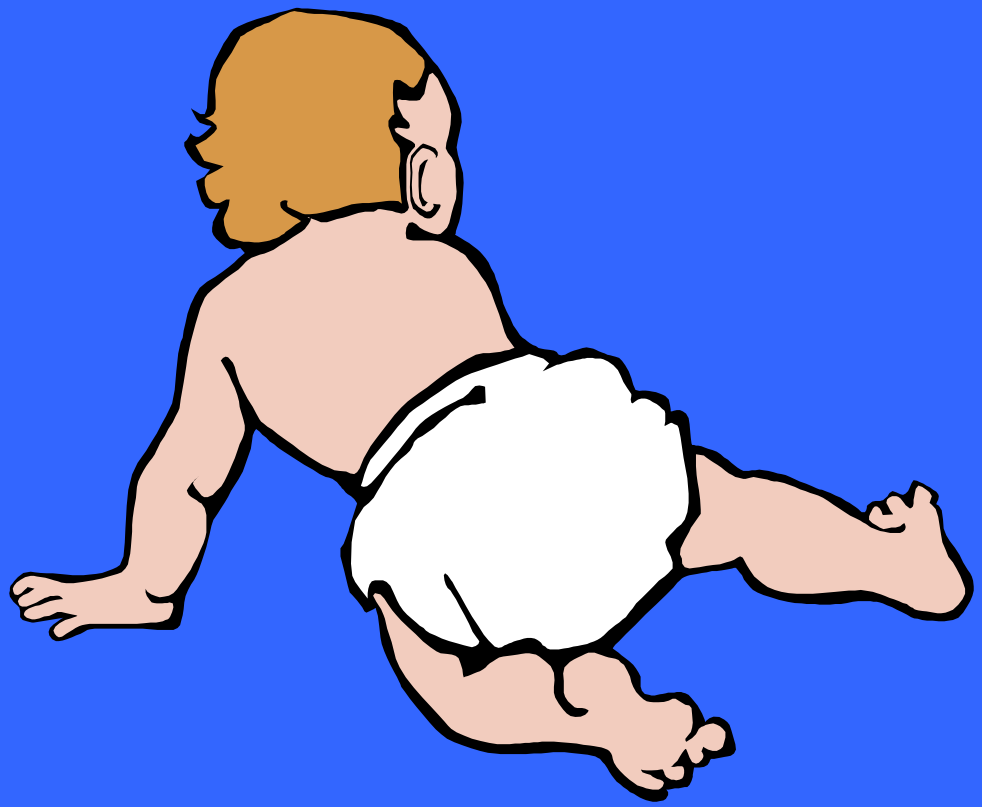
Unique Aspects of Child Exposure:
Behavioral Patterns

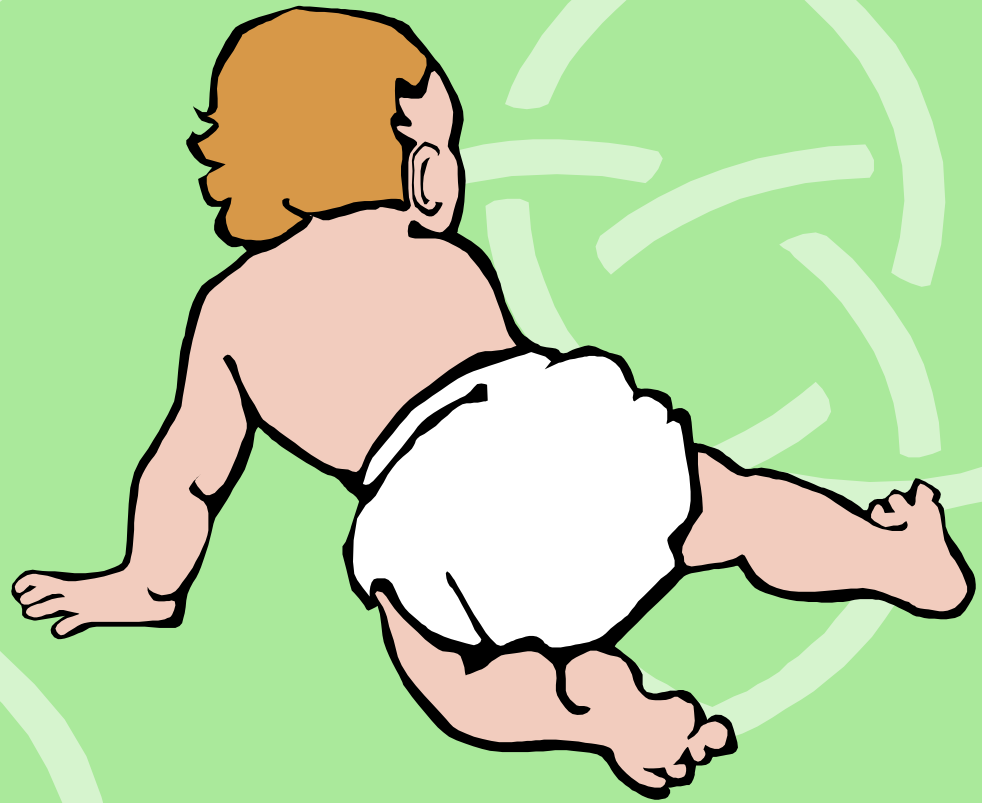
Detailed table in Armstrong et al., 2000

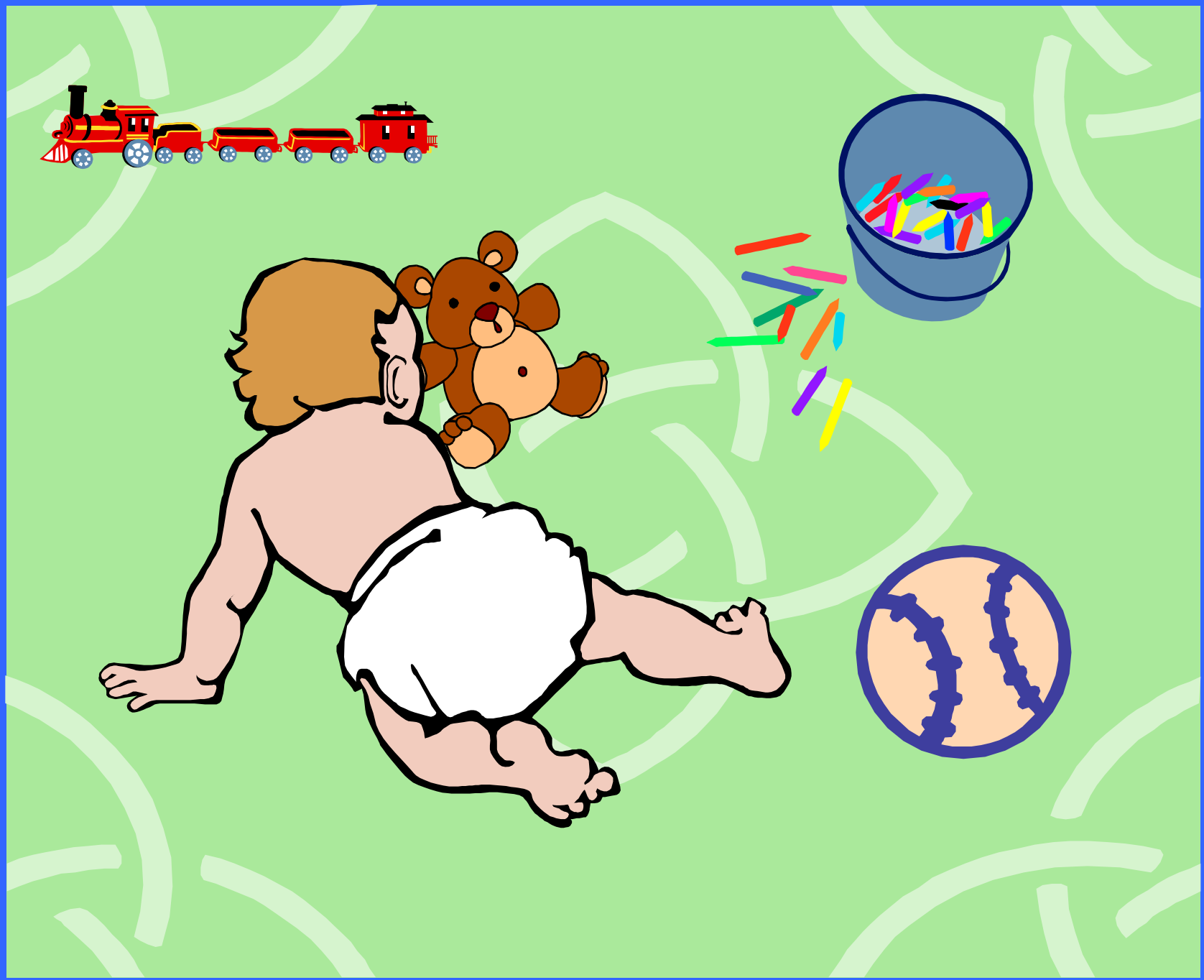
Examples include....











Information Needed

In General -

- Hazard data, physical & chemical properties, & chemical uses for screening (Screening Information Data Set)
- Physiological factors
- Air, water, beverage, food intake & preferences
- Time & activity data
- Age-bracket specific data
- Chemical-specific media concentration data

Information Needed

More specific and more detailed data are needed for each subsequent and more refined step

Information Sources for Assessing Children's Exposure

- Exposure Factors:
  - EPA Leadership: exposure factors handbook, workshops, activity database
- Chemical Concentration Data:
  - Manufacturers, "grey" & scientific literature, databases (e.g. HSDB)
- Modeling Tools to Estimate Exposure:
  - ACC sponsored review

Overall Process

- Begin with less complex, default driven screening methods
- As necessary, reduce uncertainty in exposure estimates
  - proceed to more complex, data-driven chemical and scenario specific methods
- When available, replace default assumptions with actual data
- Is consistent with EPA EA guidelines

Tiered Approach

- Chemical Selection
- Initial Margin of Exposure (MOE)
- Refined MOE

Chemical Selection

(Note: differs from VCCEP Pilot approach)

Hazard and Exposure Components:

- Moderate to high hazard
- Present at sufficient levels in child's environment

Both criteria should be met to move to next tier

Selection: Initial Hazard Information

NOAEL / LOAEL or other Hazard Metric

- No Observed Adverse Effect Level or Lowest Observed Adverse Effect Level
  - From adequate quality data
  - Child relevant endpoints when available
  - Adjusted with appropriate safety factors
- ADI or RfD may be used if available and if appropriately derived

Selection: Is the Chemical Present in the Environment of Children?

- Present at sufficient levels in:
  - Foods children eat & drink, or
  - Residential, school or outdoor air, or
  - Products children use & having physical-chemical properties allowing transfer, or
  - Soil & dust in & around the child's environment, or
  - Tissues of children

Selection: What Does “Present at Sufficient Levels” Mean?

The phrase "sufficient levels" means at an exposure range that represents at least a fraction of a conservatively established reference quantity

- A chemical’s properties and uses may limit or essentially eliminate exposure
- Detectable is not equivalent to sufficient
- Understanding of “background / natural” levels

Initial MOE

- Develop a conservative estimate of exposure
- Calculate initial Margin of Exposure (MOE):

$$\text{MOE} = \frac{\text{NOAEL}}{\text{Exposure}}$$

- If initial MOE is high, no further action necessary
- If initial MOE is low, go to next step

Acceptable MOE should consider assumptions, uncertainties in exposure and hazard data

Refined MOE

- Develop a refined exposure estimate
  - more accurate measured or modeled data
- Calculate a refined MOE
- If MOE is high, no further action required
- If MOE is low, use value to prioritize the chemical for further evaluation

As before, acceptable MOE should consider assumptions, uncertainties in estimate

Conclusions

- Sophistication of the exposure assessment needs to be aligned with:
  - the overall risk characterization goals
  - the hazard data
- Process needs to be flexible
  - varied exposure scenarios
  - varied exposure assessment goals
- Transparency and logic are key

Conclusions

- Meets the stated goal:
  - to efficiently identify the substances and scenarios that present the highest potential risks to children